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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,783	10/22/1999	DENNIS GONSALVES	19603/10303-	2343

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EXAMINER

MEHTA, ASHWIN D

ART UNIT

PAPER NUMBER

1638

12

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/426,783

Applicant(s)

GONSALVES ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-18 is/are pending in the application.
- 4a) Of the above claim(s) 10-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 1999 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner..

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 & 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 4-9 in Paper No. 11, received 27 March 2003 is acknowledged. The traversal is on the ground(s) that the claims of the present application are closely related and therefore require common areas of search and consideration. This is not found persuasive because the methods of the different groups involve different steps, which would require different searches.

Claims 10-18 have been withdrawn from consideration for being drawn to a non-elected invention. The requirement is still deemed proper and is therefore made FINAL.

Drawings

2. **INFORMATION ON HOW TO EFFECT DRAWING CHANGES-NOTE THAT THIS REPLACES THE INFORMATION THAT APPEARS ON THE BACK OF THE ATTACHED FORM PTO-948.**

Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Corrections other than Informalities Noted by Draftsperson on form PTO-948.

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All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Information Disclosure Statement

4. The listing for "Peters, D., et al. "The Biology of Tospoviruses" in the IDS submitted 22 October 1999 has been lined through because it is not in proper format. The information in the reference has been considered. However, the listing is improper because the date of publication is not present, and is not printed on the reference itself.

Claim Objections

5. Claims 5 and 9 are objected to for the following minor informalities:

In claim 5, line 1: the article "A" should be --The--.

In claim 9, line 2, the recitation "a DNA" should be --the DNA--.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 4-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-6, 8-22 of U.S. Patent No. 6,329,568 ('568).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims encompass the subject matter of the claims of the instant application.

The claims of '568 encompass isolated DNA molecules that encode non-translatable mRNA coding for polypeptides that are at least about half the length of the nucleocapsid protein of any Tospovirus; a recombinant DNA expressing system containing the DNA molecule; transgenic plant cells and plants comprising the isolated DNA molecule; and a method of producing Tospovirus resistant plants by transforming a plant cells with the DNA molecule. The Tospovirus can be TSVW-10W or TSWV-BL. The instant claims indicate that the mRNA encoded by the DNA molecule is maintained at a density reading of 15-50. The instant claims indicates that the DNA molecule, when transformed into a plant cell, is capable of transcribing into mRNA that exists at a low level density reading of 15-50. The patented claims do not state that such an embodiment is excluded, and therefore encompass it.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 4-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4: the recitation “capable of transcription” in line 1 renders the claim indefinite. It is not clear what is meant by “capable of.” It is not clear whether or not the DNA molecule is to be transcribed, if it comprises a promoter, etc. The metes and bounds of the claim are not clear.

Further in claim 4: the recitation “modified from a form...so that it does not translate into the nucleocapsid protein” in lines 2-3 renders the claim indefinite. It is not exactly clear what is intended by this recitation. In line 3, the claim indicates that the modified mRNA does not translate to the nucleocapsid protein. The recitation does not make clear whether the mRNA is untranslatable at all, or if the modified mRNA encodes another product that is produced, etc.? It is suggested that the claim be amended to clearly indicate that the mRNA is untranslatable.

In claims 4 and 9: the claims contain the trademark/trade name “Hewlett ScanJet and Image Analysis Program”. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present

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case, the trademark/trade name is used to identify/describe a software program and, accordingly, the identification/description is indefinite.

In claims 6 and 7: there is improper antecedent basis in the claims for the recitation "a heterologous DNA molecule according to claim 4". Claim 4 does not make any mention about the DNA molecule being heterologous to anything. It is suggested that claims 6 and 7 be amended to indicate that the DNA of claim 4 is heterologous to the expression system or the cell.

In claim 8: the recitation "plant containing the DNA molecule" renders the claim indefinite. The claim does not clearly indicate that the DNA molecule of claim 4 is the transferred DNA. It is suggested that the term "containing" be replaced with --transformed with-

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 4-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any isolated DNA molecule capable of transcription to a messenger RNA which is modified from a form encoding a nucleocapsid

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protein of an L serogroup Tospovirus so that it does not translate to the nucleocapsid protein, wherein, when the DNA is transformed into a plant cell, it is capable of being transcribed into mRNA which exists at low level density reading of 15-50; or wherein said DNA molecule wherein the Tospovirus is TSWV-10W or TSWV-BL; or an expression system comprising an expression vector and said isolated DNA molecule; or a transformed plant cell or plant comprising said DNA molecule; or a method of treating a plant cell, comprising transforming a plant cell with the isolated DNA molecule and transcribing the DNA molecule under conditions effective to maintain the mRNA in the plant cell at low level density readings of 15-50, wherein the plant cell acquires resistance to an L serogroup Tospovirus.

The specification indicates that DNA sequence encoding an untranslatable transcript of the nucleocapsid (N) gene of isolate TSWV-BL was constructed, in which a frameshift mutation and several termination codons were inserted immediately after the translation initiation codon. The DNA sequence was operably linked to the CaMV 35S promoter and transformed into tobacco plants. Transformed plants expressing the untranslatable N mRNA at low levels were resistant to infection by Tospovirus isolates TSWV-BL and TSWV-10W, but not INSV-Beg and TSWV-B. Transformed plant expressing the untranslatable N mRNA at high levels remained susceptible to all viruses tested (page 45, line 25 to page 53, line 9). The specification indicates that DNA molecules consisting of either the first or second half of the untranslatable N gene were produced, placed downstream of the CaMV 35S or the double CaMV 35S promoter and introduced into *Nicotiana benthamiana*. Transgenic plants showed varying levels of resistance to TSWV-BL (page 53, line 10 to page 57, line 25).

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However, the specification does not describe isolated DNA molecules capable of transcription to mRNA that is modified from that encoding a nucleocapsid protein of an L serogroup Tospovirus, and which is untranslatable, and wherein the mRNA exists in plant cells at low level density readings of 15-50, other than those having coding sequences for at least half of the nucleocapsid protein. The specification does not correlate any portions of the sequences of 5' or 3' halves of the L serogroup Tospovirus nucleocapsid mRNA sequences to the function of conferring L serogroup Tospovirus resistance to plants. Further, claim 4 does not correlate any function to the isolated DNA molecules. The specification does not correlate any function with the untranslatable transcript of the TSWV-BL isolate N gene and the untranslatable N gene halves, discussed above, except for the function of conferring resistance to plants against L-serotype Tospoviruses. See Fiers 25 USPQ 2d (CAFC 1993) at 1606, which states that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". Further, the specification admits that transgenic plants expressing about one-half of the N gene sequence was found resistant to the virus (page 53, lines 22-24). Given the breadth of the claims encompassing any type of modification of DNA molecules encoding any nucleocapsid protein of any L serogroup Tospovirus, such that nucleocapsid protein is not produced, and lack of guidance as discussed above, the specification fails to provide an adequate written description of the multitude of isolated DNA molecules encompassed by the claims.

9. Claims 4-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated DNA molecules encoding the about one-half of an

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untranslatable L serogroup Tospovirus nucleocapsid protein transcript, does not reasonably provide enablement for isolated DNA molecules that have been modified in any other way such that the encoded mRNA does not translate to the nucleocapsid protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards any isolated DNA molecule capable of transcription to a messenger RNA which is modified from a form encoding a nucleocapsid protein of an L serogroup Tospovirus so that it does not translate to the nucleocapsid protein, wherein, when the DNA is transformed into a plant cell, it is capable of being transcribed into mRNA which exists at low level density reading of 15-50; or wherein said DNA molecule wherein the Tospovirus is TSWV-10W or TSWV-BL; or an expression system comprising an expression vector and said isolated DNA molecule; or a transformed plant cell or plant comprising said DNA molecule; or a method of treating a plant cell, comprising transforming a plant cell with the isolated DNA molecule and transcribing the DNA molecule under conditions effective to maintain the mRNA in the plant cell at low level density readings of 15-50, wherein the plant cell acquires resistance to an L serogroup Tospovirus.

As discussed above, the specification teaches that a DNA sequence encoding an untranslatable transcript of the nucleocapsid (N) gene of isolate TSWV-BL was constructed, in which a frameshift mutation and several termination codons were inserted immediately after the translation initiation codon. The DNA sequence was operably linked to the CaMV 35S promoter and transformed into tobacco plants. Transformed plants expressing the untranslatable N mRNA at low levels were resistant to infection by Tospovirus isolates TSWV-BL and TSWV-10W, but

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not INSV-Beg and TSWV-B. Transformed plant expressing the untranslatable N mRNA at high levels remained susceptible to all viruses tested (page 45, line 25 to page 53, line 9). The specification teaches that DNA molecules consisting of either the first or second half of the untranslatable N gene were produced, placed downstream of the CaMV 35S or the double CaMV 35S promoter and introduced into *Nicotiana benthamiana*. Transgenic plants showed varying levels of resistance to TSWV-BL (page 53, line 10 to page 57, line 25).

However, the specification does not teach isolated DNA molecules that were modified in any other way such that they produce mRNAs that do not translate into L serogroup Tospovirus nucleocapsid proteins, and that confer L serogroup Tospovirus resistance when transcribed in transgenic plants. The specification does not provide any guidance as to the other modifications that one skilled in the art may make to produce the claimed DNA molecules. The specification does not teach any other modifications of L serogroup Tospovirus nucleocapsid coding sequences, or the sequences that are essential to the functional properties of the claimed DNA molecules. In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine other modifications that can be made to L serogroup Tospovirus nucleocapsid protein-coding sequences such that they encode mRNAs that do not translate to nucleocapsid proteins. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. Further, as mentioned above, the specification admits that transgenic plants expressing about one-half of the N gene sequence was found resistant to the virus (page 53, lines 22-24). Given the breadth of the claims encompassing any type of modification of DNA molecules encoding any nucleocapsid protein of any L

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serogroup Tospovirus, such that nucleocapsid protein is not produced, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

10. Claims 4-9 are rejected.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

June 13, 2003


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER